UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ALBANY MOLECULAR RESEARCH, INC. and SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

Civil Action No. 09-4638(GEB/MCA)

٧.

DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,

Defendants.

STIPULATION AND ORDER

WHEREAS, Plaintiffs Albany Molecular Research, Inc. and sanofi-aventis U.S. LLC (collectively, "Plaintiffs") brought this case for infringement of U.S. Patent No. 7,390,906 ("the '906 patent") against defendants Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc.'s (collectively, "Defendants" or "DRL");

WHEREAS, Plaintiffs moved to preliminarily enjoin DRL from launching commercial sales in the United States of its 180 mg fexofenadine hydrochloride / 240 mg pseudoephedrine hydrochloride extended release tablet products under Abbreviated New Drug Application No. 79-043, contending that those products infringe, or contribute to or induce infringement of the '906 patent;

WHEREAS, after consideration of the parties' briefing and expert and party declarations, and after conducting a hearing during which the Court heard testimony from fact and expert witnesses and argument of counsel, including on the issue of claim construction, this Court on June 14, 2010, granted Plaintiffs' application for a preliminary injunction (D.E. 162), tentatively ruling that the claims of the '906 patent, including the term "providing a regioisomer of the following formula ..." (the "Claim Term"), are "unambiguous and not in need of construction" and that "a person of ordinary skill in the art would understand" that the "regioisomer of the following formula ..." of the claims "could be provided and converted in a regioisomeric mixture – without any requirement that it be in pure or substantially pure form";

WHEREAS, after consideration of the parties' claim construction submissions including the Joint Claim Construction and Prehearing Statement, opening *Markman* claim construction briefs, responsive *Markman* claim construction briefs, supporting expert declarations and exhibits, and after conducting a *Markman* Hearing on November 10, 2010, this Court on January 13, 2011, issued its *Markman* Opinion and Order (D.E. 381) construing the disputed claim terms of, *inter alia*, the '906 patent, in which the Court adopted DRL's proposed construction of the Claim Term, and construed the Claim Term to mean "the regioisomer having the structure shown in the formula is present in at least 98% purity with respect to all impurities";

WHEREAS, Plaintiffs object to the Court's construction of the Claim Term as set forth in its January 13, 2011, *Markman* Opinion and Order, believe that the findings on claim construction set forth therein are incorrect, and intend to appeal the Court's claim construction, and the parties understand and agree that the present stipulation does not waive any party's rights under the Federal Rules of Civil Procedure, Rules of Appellate Procedure or any Local Civil Rule of this District;

WHEREAS, Plaintiffs stipulate that, based upon the Court's construction of the Claim Term in the '906 patent as set forth in its January 13, 2011, *Markman* Opinion and Order, Plaintiffs cannot carry their burden of proving infringement of the '906 patent by any of the DRL products identified in the Amended Complaint (D.E. 35);

WHEREAS, prior to the Court's January 13, 2011, *Markman* Opinion and Order, on January 10, 2011, the parties submitted a final pretrial order (D.E. 363), and on January 17, 2011, the parties submitted a corrected final pretrial order (D.E. 384);

WHEREAS, during a January 21, 2011, final pretrial conference, in light of the Court's construction of the Claim Term in the '906 patent as set forth in its January 13, 2011, *Markman* Opinion and Order, Plaintiffs raised the possibility of pursuing the present Stipulation and Order so as to immediately appeal the Court's claim construction in lieu of proceeding with trial on January 31, 2011, because Plaintiffs are not able to meet their burden of proving infringement at trial under the Court's claim construction;

WHEREAS, as DRL stated during the January 21, 2011, final pretrial conference, DRL is and was prepared to try the issues set forth in the Pretrial Order;

WHEREAS, Plaintiffs are entering this Stipulation for the purpose of taking an immediate appeal to the Federal Circuit on the Court's construction of the Claim Term in the '906 patent as set forth in its January 13, 2011, *Markman* Opinion and Order;

WHEREAS, Plaintiffs have posted security with the Court in the amount of \$40,000,000 against the possibility that DRL was wrongfully enjoined or restrained by this Court's June 14, 2010, Order;

WHEREAS, in reliance on this Stipulation, and the lifting of the preliminary injunction, DRL has agreed to forego the scheduled trial;

NOW, THEREFORE, the parties stipulate and agree as follows:

1. Plaintiffs stipulate that, based upon the Court's construction of the Claim Term in the '906 patent as set forth in its January 13, 2011, *Markman* Opinion and Order, Plaintiffs

cannot carry their burden of proving infringement of the '906 patent by any of the DRL products identified in the Amended Complaint (D.E. 35);

- 2. Based upon the Court's construction of the Claim Term in the '906 patent as set forth in its January 13, 2011, *Markman* Opinion and Order, and for the purposes of allowing the immediate appeal of such construction, the parties request that the Court enter a final judgment against Plaintiffs and in favor of DRL on Plaintiffs' claim that DRL infringes the '906 patent;
- 3. All of DRL's remaining counterclaims shall be dismissed without prejudice, and DRL shall have the right to reinstate its counterclaims by letter application to the Court;
- 4. Upon entry of final judgment on Plaintiffs' infringement claim, Plaintiffs may take an immediate appeal to the Federal Circuit of that final judgment based solely on Plaintiffs' objection to the Court's construction of the Claim Term in the '906 patent as set forth in its January 13, 2011, *Markman* Opinion and Order;
- 5. No party shall use this Stipulation for any purpose in this litigation unless authorized by the Court upon application, except that this Stipulation may be part of the appellate record;
- 6. Provided Plaintiffs file a timely Notice of Appeal from the final judgment to be entered pursuant to this Stipulation and Order, there shall be no application for a decision on the posted security until after resolution by the Federal Circuit of Plaintiffs' appeal of this Court's construction of the Claim Term without prior approval of the Court;
- 7. The parties shall preserve all evidence with respect to DRL's claim for damages based on DRL's claim that it was wrongfully enjoined by this Court's June 14, 2010, Order;
- 8. Upon execution of this Stipulation and Order by the parties and the Court, the preliminary injunction (D.E. 162) shall be automatically dissolved;

9. The security posted by Plaintiffs shall remain in place until further order of the

Court;

10. If the Federal Circuit affirms this Court's construction of the Claim Term or if

Plaintiffs' appeal is otherwise disposed of in a manner that does not alter the Court's

construction of the Claim Term: (a) Plaintiffs shall not challenge the final judgment of non-

infringement entered pursuant to this Stipulation and Order unless such challenge is allowed

under the applicable Federal Rules of Civil Procedure, including Rule 60; and (b) DRL shall

have thirty (30) days from issuance of the Federal Circuit's mandate on Plaintiffs' appeal or from

receipt of written notice of any other disposition of the appeal to (1) apply for costs, attorneys'

fees and related nontaxable expenses pursuant to Fed. R. Civ. P. 54(d) or other authority, and (2)

serve and file a Bill of Costs and Disbursements pursuant to Local Civ. R. 54.1;

Any trial in this or any other action against DRL for infringement of the '906 11.

patent, including any trial in the event of remand, shall be a non-jury trial.

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IT IS on this 28day of January, 2011, hereby, **ORDERED**:

- 1. The foregoing Stipulation is, in all things, ADOPTED;
- 2. Judgment of noninfringement of the '906 patent by Defendants is **GRANTED**;
- 3. All of Defendants' pending counterclaims in this case are **DISMISSED** without prejudice;
- 4. There being no remaining claims at issue in this case, the Court directs the Clerk to enter final judgment in accordance with this Order in favor of Defendants on Plaintiffs' claim for infringement of the '906 patent and dismiss all other claims in this case against and by Defendants without prejudice and with leave to reinstate by letter application to the Court;
- 5. Immediately upon execution of this Order, the preliminary injunction entered by this Court on June 14, 2010, (D.E. 162) is dissolved;
- 6. Provided Plaintiffs file a timely Notice of Appeal from the final judgment to be entered pursuant to this Stipulation and Order, there shall be no application for a decision on the posted security until after resolution by the Federal Circuit of Plaintiffs' appeal of this Court's construction of the Claim Term without prior approval of the Court;
- 7. The parties shall preserve all evidence with respect to Defendants' claim for damages based on Defendants' claim that it was wrongfully enjoined by this Court's June 14, 2010 Order;
- 8. The security posted by Plaintiffs shall remain in place until further order of the Court;
- 9. If the Federal Circuit affirms this Court's construction of the Claim Term or if Plaintiffs' appeal is otherwise disposed of in a manner that does not alter the Court's construction of the Claim Term: (a) Plaintiffs shall not challenge the final judgment of non-

infringement entered pursuant to this Stipulation and Order unless such challenge is allowed under the applicable Federal Rules of Civil Procedure, including Rule 60; and (b) Defendants shall have thirty (30) days from issuance of the Federal Circuit's mandate on Plaintiffs' appeal or from receipt of written notice of any other disposition of the appeal to (1) apply for costs, attorneys' fees and related nontaxable expenses pursuant to Fed. R. Civ. P. 54(d) or other authority, and (2) serve and file a Bill of Costs and Disbursements pursuant to Local Civ. R. 54.1;

- 10. The above Stipulation does not waive any party's rights under the Federal Rules of Civil Procedure, Rules of Appellate Procedure or any Local Civil Rule of this District; and
- 11. Any trial in this or any other action against Defendants for infringement of the '906 patent, including any trial in the event of remand, shall be a non-jury trial.

Honorable Garrett E. Brown, Jr., Chief Judge, U.S.D.J.